

# **EXHIBIT 41**

**From:** Dempsey, Michele [GPSUS]  
**To:** Daly, John [NORUS] (JDaly6@its.jnj.com)  
**Sent:** 1/28/2015 6:31:34 PM  
**Subject:** FW: DEA at JOM KDC (28-JAN-2014)

I want a champion like Mike Griffith.

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**From:** Griffith, Mike [GPSUS]  
**Sent:** Wednesday, January 28, 2015 1:21 PM  
**To:** Dempsey, Michele [GPSUS]  
**Subject:** RE: DEA at JOM KDC (28-JAN-2014)

AMEN to that book!!!!!!!

Mike Griffith  
Director, Network & Integration Programs  
CLS North America  
1-781-264-3574 (mobile)  
[mgriffit@its.jnj.com](mailto:mgriffit@its.jnj.com)

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**From:** Dempsey, Michele [GPSUS]  
**Sent:** Wednesday, January 28, 2015 1:20 PM  
**To:** Griffith, Mike [GPSUS]; Levitt, Michael [NORUS]  
**Cc:** Williams, Chris [GPSUS]; Hummel, Brad [SLCUS]  
**Subject:** RE: DEA at JOM KDC (28-JAN-2014)

Thank you Mike!

Mike even emailed Jason to check on the inspection. I appreciate your support and look forward to a smooth handover to Brad. Critical to the success is making sure that inspection readiness binder is kept up to date.

Best of luck on your new role!  
Regards,  
Michele

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**From:** Griffith, Mike [GPSUS]  
**Sent:** Wednesday, January 28, 2015 1:18 PM  
**To:** Levitt, Michael [NORUS]; Dempsey, Michele [GPSUS]  
**Cc:** Williams, Chris [GPSUS]; Hummel, Brad [SLCUS]  
**Subject:** FW: DEA at JOM KDC (28-JAN-2014)

Michelle,  
I wanted to say that this would not have been as successful as it was if not for the leadership and guidance provided by Mike. He has helped prepare KDC for these events and all the preparation sometimes goes unnoticed. Thanks to Mike for his passion and support to JOM/KDC!!

Mike

Mike Griffith  
Director, Network & Integration Programs  
CLS North America  
1-781-264-3574 (mobile)  
[mgriffit@its.jnj.com](mailto:mgriffit@its.jnj.com)

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**From:** Wick, Martha [GPSUS]  
**Sent:** Wednesday, January 28, 2015 12:22 PM  
**To:** Miller, Nancy [GPSUS]; Khater, Maroun [CPCUS]; Girardi, Glenn A. [SLC]; Garcia, Zeuxis [GPSUS]; Lucarelli, Joe [HCSUS]; Allison, Liz [ASPUS]; Federico, Peter [GPSUS]; Merritt, Elaine [GPSUS]; Pfederer, Christine [GPSUS]; Szwarc, Michael [GPSUS]; Williams-Dunn, Leslie [SLCUS]; Lopez, Andres [HCSUS]; Griffith, Mike [GPSUS]; Harry, George [SLC]; Turso, Mary [HCS]; Bulone, Mike [GPSUS]; Iwanski, Yvonne [OMPUS]; Dysart, Art [GPSUS]; Sedlatschek, Mike [GPSUS]; Lovell, Rick [JSGUS];



Stately, Darlene [GPSUS]; Baratta, Mike [JSGUS]; Vandergriff, Justin [GPSUS]; Thostesen, Eric [JSGUS]; Keenan, Chris [GPSUS]; Peterson, Greg [GPSUS]; Pflederer, Christine [GPSUS]; Garcia, Zeuxis [GPSUS]; Logsdon, Angie [GPSUS]; Pulido, Flor [GPSUS Non-J&J]; Naranjo, Fanny [GPSUS]; Maiolino, Cindy [GPSUS]; Levitt, Michael [NORUS]; Thostesen, Eric [JSGUS]; Bourgoin, Josee [CPCUS]; Pringle, John [GPSUS]; Davis, Kenneth [GPSUS]; Freedman, Michael [HCS]; Mincarelli, Alfred [GPSUS]; Pendigraph, Kevin [JSGUS Non J&J]; Hood, Mark [GPSUS]; Pawling, Ryan [GPSUS]; Christie, Joseph [GPSUS]; Helfrick, Robert [MCCUS]; Williams-Dunn, Leslie [SLCUS]; Dolley, Joe [LFSUS]; McElligott, Susan [GPSUS]; Levitt, Michael [NORUS]; McAllister, Kevin [HCSUS]; Hummel, Brad [SLCUS]; Williams, Chris [GPSUS]; Corum, Belinda [GPSUS]; Bottom, Rebecca [GPSUS]; Phee, Kathy [SLCUS]; Irvin, Vincent [GPSUS]; Sedlatschek, Mike [GPSUS]; Dempsey, Michele [GPSUS]; Feltre, Jamie [SLCUS]; Dinunzi, Dwight [GPSUS]; Bourgoin, Josee [CPCUS]

**Subject:** RE: DEA at JOM KDC (28-JAN-2014)

The DEA just left. There were no observations.

Closing comments –

- No observations; all good; e- records are really good, easy to ready
- If any changes in structure or security let them know first
  - Ken D. - will add additional cameras out front; will create letter, send to them, await feedback before proceeding
- Should see them again in 2 yrs

Here is a brief inspection summary:

- **Date:** 28-JAN-2015
- **Inspection Day:** 2
- **Regulatory Agency:** DEA
- **Investigators:** Pat Sowers, Jason R. Smith, Chris Skaggs
- **Site/Location:** JOM KDC /Shepherdsville, KY
- **Reason for Inspection/Type:** Routine inspection
- **Potential Concerns:** None identified
- **Issues Identified by Investigators as Potential Observations:** None
- **Primary Areas Reviewed Today:**
  - Security
    - 1. Alarm testing
  - Inventory
    - 1. For imported materials (18-AUG-2014 through 28-JAN-2015) – not noted yesterday
      - cage/vault inventory quantity confirmation -

Product Name	SKUs
Tramadol HCl ER 300mg	1014709033
Tramadol HCl ER 100mg	1014709013
Ultram ER 200mg	5045865830
Ultram ER 300mg	5045865730
Ultram ER 100mg	5045865330

- 1. Random 2 mo. sampling of 222 forms
- Review of documentation requested yesterday - provided, also -
  - Detailed info. on vault/cage access list (addresses, phone #s)
  - Contact info. for two [2] random customers (Cardinal and McKesson)
  - Name /address for Pegasus and Stericycle
  - Address of Exporter (Canada)
- Updated info. from the 2013 inspection report
- **Open Discussion Points:** None identified
- **Primary Areas for Review Next Day:** N/A
- **Daily Summary Issued By:** Martha Wick

Many thanks to everyone who participated/assisted with this inspection.

Thank you.  
Martha Wick

Senior Manager, Quality Assurance

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the sender, so that Johnson & Johnson can arrange for proper delivery, and then please delete the message from your inbox. Thank you.

**From:** Wick, Martha [GPSUS]

**Sent:** Wednesday, January 28, 2015 8:50 AM

**To:** Miller, Nancy [GPSUS]; Khater, Maroun [CPCUS]; Girardi, Glenn A. [SLC]; Garcia, Zeuxis [GPSUS]; Lucarelli, Joe [HCSUS]; Allison, Liz [ASPUS]; Federico, Peter [GPSUS]; Merritt, Elaine [GPSUS]; Pfederer, Christine [GPSUS]; Szwarc, Michael [GPSUS]; Williams-Dunn, Leslie [SLCUS]; Lopez, Andres [HCSUS]; Griffith, Mike [GPSUS]; Harry, George [SLC]; Turso, Mary [HCS]; Bulone, Mike [GPSUS]; Iwanski, Yvonne [OMPUS]; Dysart, Art [GPSUS]; Sedlatschek, Mike [GPSUS]; Lovell, Rick [JSGUS]; Stately, Darlene [GPSUS]; Baratta, Mike [JSGUS]; Vandergriff, Justin [GPSUS]; Thostesen, Eric [JSGUS]; Keenan, Chris [GPSUS]; Peterson, Greg [GPSUS]; Pfederer, Christine [GPSUS]; Garcia, Zeuxis [GPSUS]; Logsdon, Angie [GPSUS]; Pulido, Flor [GPSUS Non-J&J]; Naranjo, Fanny [GPSUS]; Maiolino, Cindy [GPSUS]; Levitt, Michael [NORUS]; Thostesen, Eric [JSGUS]; Bourgoin, Josee [CPCUS]; Pringle, John [GPSUS]; Davis, Kenneth [GPSUS]; Freedman, Michael [HCS]; Mincarelli, Alfred [GPSUS]; Pendigraph, Kevin [JSGUS Non J&J]; Hood, Mark [GPSUS]; Pawling, Ryan [GPSUS]; Christie, Joseph [GPSUS]; Helfrick, Robert [MCCUS]; Williams-Dunn, Leslie [SLCUS]; Dolley, Joe [LFSUS]; McElligott, Susan [GPSUS]; Levitt, Michael [NORUS]; McAllister, Kevin [HCSUS]; Hummel, Brad [SLCUS]; Williams, Chris [GPSUS]; Corum, Belinda [GPSUS]; Bottom, Rebecca [GPSUS]; Phee, Kathy [SLCUS]; Irvin, Vincent [GPSUS]; Sedlatschek, Mike [GPSUS]; Dempsey, Michele [GPSUS]; Feltre, Jamie [SLCUS]; Wick, Martha [GPSUS]; Dinunzi, Dwight [GPSUS]; Bourgoin, Josee [CPCUS]

**Subject:** DEA at JOM KDC (28-JAN-2014)

Good morning! The DEA has just arrived on site for today.

Thank you.

Martha Wick

Senior Manager, Quality Assurance

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**From:** Wick, Martha [GPSUS]

**Sent:** Tuesday, January 27, 2015 11:52 AM

**To:** Miller, Nancy [GPSUS]; Khater, Maroun [CPCUS]; Girardi, Glenn A. [SLC]; Garcia, Zeuxis [GPSUS]; Lucarelli, Joe [HCSUS]; Allison, Liz [ASPUS]; Federico, Peter [GPSUS]; Merritt, Elaine [GPSUS]; Pfederer, Christine [GPSUS]; Szwarc, Michael [GPSUS]; Williams-Dunn, Leslie [SLCUS]; Lopez, Andres [HCSUS]; Griffith, Mike [GPSUS]; Harry, George [SLC]; Turso, Mary [HCS]; Bulone, Mike [GPSUS]; Iwanski, Yvonne [OMPUS]; Dysart, Art [GPSUS]; Sedlatschek, Mike [GPSUS]; Lovell, Rick [JSGUS]; Stately, Darlene [GPSUS]; Baratta, Mike [JSGUS]; Vandergriff, Justin [GPSUS]; Thostesen, Eric [JSGUS]; Keenan, Chris [GPSUS]; Peterson, Greg [GPSUS]; Pfederer, Christine [GPSUS]; Garcia, Zeuxis [GPSUS]; Logsdon, Angie [GPSUS]; Pulido, Flor [GPSUS Non-J&J]; Naranjo, Fanny [GPSUS]; Maiolino, Cindy [GPSUS]; Levitt, Michael [NORUS]; Thostesen, Eric [JSGUS]; Bourgoin, Josee [CPCUS]; Pringle, John [GPSUS]; Davis, Kenneth [GPSUS]; Freedman, Michael [HCS]; Mincarelli, Alfred [GPSUS]; Pendigraph, Kevin [JSGUS Non J&J]; Hood, Mark [GPSUS]; Pawling, Ryan [GPSUS]; Christie, Joseph [GPSUS]; Helfrick, Robert [MCCUS]; Williams-Dunn, Leslie [SLCUS]; Dolley, Joe [LFSUS]; McElligott, Susan [GPSUS]; Levitt, Michael [NORUS]; McAllister, Kevin [HCSUS]; Hummel, Brad [SLCUS]; Williams, Chris [GPSUS]; Corum, Belinda [GPSUS]; Bottom, Rebecca [GPSUS]; Phee, Kathy [SLCUS]; Irvin, Vincent [GPSUS]; Sedlatschek, Mike [GPSUS]; Dempsey, Michele [GPSUS]

**Subject:** RE: DEA at JOM KDC (27-JAN-2014)

The DEA just left for the day. They will be back before 9am (~845am) tomorrow.

#### INSPECTION COMMUNICATION:

INSPECTING REGULATORY BODY/BODIES	<b>DEA:</b>  Pat Sowers; Diversion Investigator; Louisville District Office  Jason R. Smith; Diversion Investigator; Louisville District Office  Chris Skaggs; Diversion Investigator; Louisville District Office
SCOPE OF INSPECTION/PRODUCTS INVOLVED & STAGE OF MANUFACTURE (e.g. API, fill/finish, packaging, etc.)	Controlled substances

TYPE OF INSPECTION (e.g. GMP, Pre-Approval, Directed)	Routine inspection
DATE (anticipated or actual start date)	27-JAN-2015 (actual start date) (~9am-11:30am)
LOCATION OF INSPECTION	KDC
ISSUES IDENTIFIED, if available	None
KEY CONTACTS (e.g. Quality Head, Inspection host/lead)	KDC: Mike Griffith, Ken Davis, Kevin Pendigraph, Nancy Miller, Joe Christie, Becky Bottoms, Belinda Corum, Martha Wick

Also, here is a brief inspection summary:

- **Date:** 27-JAN-2015
- **Inspection Day:** 1
- **Regulatory Agency:** DEA
- **Investigators:** Pat Sowers, Jason R. Smith, Chris Skaggs
- **Site/Location:** JOM KDC /Shepherdsville, KY
- **Reason for Inspection/Type:** Routine inspection
- **Potential Concerns:** None identified
- **Issues Identified by Investigators as Potential Observations:** None
- **Primary Areas Reviewed Today:**

- Licenses
- Org. charts (KDC Ops, QA; pending CL SOPs)
- Annual/biennial inventories
- Vault & cage access list
- Power of Attorneys
- Floor map
- Cage and vault inventory quantity confirmation -

Product Name	SKU
Fentanyl 12.5mcg	0781724055
Nucynta 50 mg	5045882004
Concerta ER 27mg	5045858801
Duragesic 5 x 50 mcg	5045809205
Concerta ER 36mg	5045858601
Nucynta ER 250mg	5045886401
Tramadol Hcl ER 100mg	1014709013
Tylenol w/codeine #4	5045851570

- **Open Discussion Points:** None identified
- **Primary Areas for Review Next Day:** Security alarms; all transactions for the 8 SKUs listed above 01-JAN-2014 to 27-JAN-2015; documentation requested 27-JAN
- **Daily Summary Issued By:** Martha Wick / Nancy Miller (see below)

**From:** Miller, Nancy [GPSUS]

**Sent:** Tuesday, January 27, 2015 11:43 AM

**To:** Wick, Martha [GPSUS]

**Cc:** Griffith, Mike [GPSUS]; Miller, Nancy [GPSUS]

**Subject:** DEA Notes

Attendees: Mike G, Kevin P, Joe C, Dwight, Ken D, Martha, Nancy

- Arrived at 9am
- 3 Day inspection reduced to 2 days since KDC doesn't import or export Scheduled product
- Requested Importer Lic #
- 3 Audits



1) Distribution (C. Skaggs)

2) Importer (J. Smith)

3) Exporter (P. Sowers)

- Collect the same organizational documentation for all 3 audits
- Requested: Inventory report for all Schedules Inventory
- Requested CLS QA Org Chart
- Requested CLS Ops Org Chart (up to Katherine Ross)
- Requested Suspicious Order Procedure
- Requested Destruction Procedure
- Requested Policy on Qualifying new customers
- Requested POA (noted that if an employee retired or left the company that JOM needed to resend the POA and attach it to the old POA.
- If there is a change in the security system with the new office construction the DEA (Martin Redd) needs to be notified

An EDGE2 report will be filed.

Thank you.

Martha Wick

Senior Manager, Quality Assurance

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**From:** Miller, Nancy [GPSUS]

**Sent:** Tuesday, January 27, 2015 10:29 AM

**To:** Wick, Martha [GPSUS]; Khater, Maroun [CPCUS]; Girardi, Glenn A. [SLC]; Garcia, Zeuxis [GPSUS]; Lucarelli, Joe [HCSUS]; Allison, Liz [ASPUS]; Federico, Peter [GPSUS]; Merritt, Elaine [GPSUS]; Pflederer, Christine [GPSUS]; Szwarc, Michael [GPSUS]; Williams-Dunn, Leslie [SLCUS]; Lopez, Andres [HCSUS]; Griffith, Mike [GPSUS]; Harry, George [SLC]; Mastrianni, Kaitlin [SLCUS]; Turso, Mary [HCS]; Bulone, Mike [GPSUS]; Iwanski, Yvonne [OMPUS]; Dysart, Art [GPSUS]; Sedlatschek, Mike [GPSUS]; Lovell, Rick [JSGUS]; Statel, Darlene [GPSUS]; Baratta, Mike [JSGUS]; Vandergriff, Justin [GPSUS]; Thostesen, Eric [JSGUS]; Keenan, Chris [GPSUS]; Peterson, Greg [GPSUS]; Pflederer, Christine [GPSUS]; Garcia, Zeuxis [GPSUS]; Logsdon, Angie [GPSUS]; Pulido, Flor [GPSUS Non-J&J]; Naranjo, Fanny [GPSUS]; Maiolino, Cindy [GPSUS]; Levitt, Michael [NORUS]; Thostesen, Eric [JSGUS]; Bourgoin, Josee [CPCUS]; Pringle, John [GPSUS]; Davis, Kenneth [GPSUS]; Freedman, Michael [HCS]; Mincarelli, Alfred [GPSUS]; McGurk, Daniel [SLCUS]; Pendigraph, Kevin [JSGUS Non J&J]; Hood, Mark [GPSUS]; Pawling, Ryan [GPSUS]; Christie, Joseph [GPSUS]; Helfrick, Robert [MCCUS]; Cousoulis, Aimee [GPSUS Non-J&J]; Cutler, Evan [JSGUS Non J&J]; Williams-Dunn, Leslie [SLCUS]; Dolley, Joe [LFSUS]; McElligott, Susan [GPSUS]; Levitt, Michael [NORUS]; McAllister, Kevin [HCSUS]; Hummel, Brad [SLCUS]; Williams, Chris [GPSUS]

**Subject:** Inspection: DEA at JOM KDC (27-JAN-2014)

#### INSPECTION COMMUNICATION:

INSPECTING REGULATORY BODY/BODIES	<b>DEA:</b>  <i>Attendee –</i>  Patrick Sowers; Diversion Investigator; Louisville District Office  Jason R. Smith; Diversion Investigator; Louisville District Office  Chris Skaggs; Diversion Investigator; Louisville District Office
SCOPE OF INSPECTION/PRODUCTS INVOLVED & STAGE OF MANUFACTURE (e.g. API, fill/finish, packaging, etc.)	Controlled substances
TYPE OF INSPECTION (e.g. GMP, Pre-Approval, Directed)	Day 1: Import, Export and Distribution Processes  Day 2: Security System Operations

DATE (anticipated or actual start date)	27-JAN-2015 (09:00am)
LOCATION OF INSPECTION	KDC
ISSUES IDENTIFIED, if available	
KEY CONTACTS (e.g. Quality Head, Inspection host/lead)	<p><i>Anticipated attendees -</i></p> <p>KDC: Mike Griffith, Martha Wick, Nancy Miller, Joe Christie, Ken Davis, Kevin Pendigraph</p> <p>DEA Compliance: Mike Levitt</p>

Thank you,  
Nancy Miller

*CLS Manager of Distribution Quality and Compliance Execution*

Desk (502) 921-5008  
Mobile (502) 645-7443  
925 Conestoga Parkway  
Shepherdsville KY 40165

**From:** Miller, Nancy [GPSUS]

**Sent:** Tuesday, January 27, 2015 9:04 AM

**To:** Wick, Martha [GPSUS]; Khater, Maroun [CPCUS]; Girardi, Glenn A. [SLC]; Garcia, Zeuxis [GPSUS]; Lucarelli, Joe [HCSUS]; Allison, Liz [ASPUS]; Federico, Peter [GPSUS]; Merritt, Elaine [GPSUS]; Pflederer, Christine [GPSUS]; Szwarc, Michael [GPSUS]; Williams-Dunn, Leslie [SLCUS]; Lopez, Andres [HCSUS]; Griffith, Mike [GPSUS]; Harry, George [SLC]; Mastrianni, Kaitlin [SLCUS]; Turso, Mary [HCS]; Bulone, Mike [GPSUS]; Iwanski, Yvonne [OMPUS]; Dysart, Art [GPSUS]; Sedlatschek, Mike [GPSUS]; Lovell, Rick [JSGUS]; Stately, Darlene [GPSUS]; Baratta, Mike [JSGUS]; Vandergriff, Justin [GPSUS]; Thostesen, Eric [JSGUS]; Keenan, Chris [GPSUS]; Peterson, Greg [GPSUS]; Pflederer, Christine [GPSUS]; Garcia, Zeuxis [GPSUS]; Logsdon, Angie [GPSUS]; Pulido, Flor [GPSUS Non-J&J]; Naranjo, Fanny [GPSUS]; Maiolino, Cindy [GPSUS]; Levitt, Michael [NORUS]; Thostesen, Eric [JSGUS]; Bourgoin, Josee [CPCUS]; Pringle, John [GPSUS]; Davis, Kenneth [GPSUS]; Freedman, Michael [HCS]; Mincarelli, Alfred [GPSUS]; McGurk, Daniel [SLCUS]; Pendigraph, Kevin [JSGUS Non J&J]; Hood, Mark [GPSUS]; Pawling, Ryan [GPSUS]; Christie, Joseph [GPSUS]; Helfrick, Robert [MCCUS]; Cousoulis, Aimee [GPSUS Non-J&J]; Cutler, Evan [JSGUS Non J&J]; Williams-Dunn, Leslie [SLCUS]; Dolley, Joe [LFSUS]; McElligott, Susan [GPSUS]; Levitt, Michael [NORUS]; McAllister, Kevin [HCSUS]; Hummel, Brad [SLCUS]; Williams, Chris [GPSUS]

**Subject:** DEA at JOM KDC (27-JAN-2014)

**Importance:** High

Dear All,

I was just informed that the DEA arrived at KDC at 9am this morning. Mike Griffith is hosting them and I will provide an update as soon as information is available.

Regards,  
Nancy

*CLS Manager of Distribution Quality and Compliance Execution*

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Mobile (502) 645-7443  
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Shepherdsville KY 40165

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